DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 2, 2014

H2 INC.
C/O FENG-YU LEE
PRINCIPAL CONSULTANT
29222 RANCHO VIEJO RD, STE 218
SAN JUAN CAPISTRANO CA 92675

Re: K141862
Trade/Device Name: Health2Sync Mobile Application and Smart Cable
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: October 13, 2014
Received: October 15, 2014

Dear Ms. Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Health2Sync Mobile Application and Smart Cable For Diabetes Management

Indications for Use *(Describe)*

Health2Sync Mobile Application is data management software that is intended for use in home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. The Health2Sync Smart Cable allows users to upload blood glucose data from compatible FDA cleared meters to the Health2Sync Mobile Application on their iPhone operating system platform.

Health2Sync Mobile Application is not intended to provide treatment decisions nor is it to be used as a substitute for professional healthcare advice.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k141862

1. Submitter's Identification:

H2 Inc.
5 Fl., No. 586, Ruiguang Rd.,
Taipei City 114, Taiwan (R.O.C.)
Contact Person: Chu-Yie Deng
Phone Number: 886-2-8797-3844
FAX Number: 886-2-8797-3923

Date Summary Prepared: November 26, 2014

2. **Contact Persons:**

Primary Contact:
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Contact Person: Chu-Yie Deng
Phone Number: 886-2-8797-3844
FAX Number: 886-2-8797-3923

3. **Name of the Device:**
Health2Sync Mobile Application and Smart Cable for Diabetes Management

4. **Device Common or Usual Name:**
Diabetes Monitoring (Blood Glucose Meter) and Data Management System (Software and adapters)

Regulation Info:

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the-Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/ Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

4. Device Description:

The Health2Sync Mobile Application and Smart Cable (Mobile App and adapters) allows the transfer of blood glucose readings from the compatible glucose meter to smartphone via Smart Cable.

The App features enable the user to view and analyze blood glucose readings from different meal time periods, other features including lifestyle diary, interpretable graphs option, inviting and sharing data with partners, and emailing reports are available for viewing and analyzing blood glucose readings within the different time slots.

The system includes: 1) Health2Sync Mobile Application (through Apple store only), 2) Smart Cable, 3) Smart Cable 3.5mm connector (optional) and 4) Smart Cable and Application Quick Start Guide

Compatible Meters include:
OMNIS Health Embrace BGMS Meter, (k113098)
OMNIS Health Embrace EVO BGMS Meter (k090043), and
Medline EvenCare G2 BGMS meter (k113208)

5. Intended Use:

Health2Sync Mobile Application is data management software that is intended for use in home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. The Health2Sync Smart Cable allows users to upload blood glucose data from compatible FDA cleared meters to the Health2Sync Mobile Application on their iPhone operating system platform.

Health2Sync Mobile Application is not intended to provide treatment decisions nor is it to be used as a substitute for professional healthcare advice.

6. Predicate Device Information:

The Health2Sync Mobile Application and Smart Cable is substantially equivalent to the predicate device noted below.

Name:	Glooko Device System for Glooko Logbook+ Application
Device Company:	Glooko, Inc.
510(K) Number:	K130886

7. Specification Comparison to Predicate Devices:

Similarities and Differences		
Item	**Health2Sync (Candidate Device)**	**Glooko Device System for Glooko Logbook+ Application (K130886)**
Intended Use / Indication(s) for Use	• For use by patients with diabetes to sync blood glucose data from compatible meters to mobile App installed on compatible iOS device(s) • Allow users to share data by emailing the report or inviting other personnel, including but not limited to healthcare provider to view the data • When mobile App is installed on a smartphone, a database can be used to store users' profiles and manage their blood glucose readings. • User needs to log in with unique user ID and password to view and organize blood glucose readings.	• For use by patients with diabetes to sync blood glucose data from compatible meters to mobile App installed on compatible iOS device(s) • Allow users to share data by emailing the report • When mobile App is installed on a smartphone, a database can be used to store users' profiles and manage their blood glucose readings • User needs to log in with unique user ID and password to view and organize blood glucose readings.
Operation System	iOS 7	iOS 5.0 and higher
Syncs with Compatible Meters	Yes	Yes

Compatible Blood Glucose Meters	• OMNIS Health Embrace BGMS Meter (Up to 300 data stored), • OMNIS Health Embrace EVO BGMS Meter (Up to 300 data stored), and • Medline EvenCare G2 BGMS meter (Up to 300 data stored)	Other BGMS meters
Connection	Audio Port	30-pin or lightning 8-pin connector (require Apple's off-the-shelf Lightning to 30-pin adapter for connection)
COM Ports Scan	None Applicable	None Applicable
Hardware 1	Smart cable	MeterSync Cable IR Adapter
Hardware 2	iPhone 4, 4S, 5 and 5S	• iPod touch: 3 and 4G • iPhone: 3GS, 4 and 4S • iPad: iPad 1, 2 and iPad 3G (Accessed in 2X mode) • iPod touch 5G, iPhone 5, iPad mini, and iPad 4G (require Apple's off-the-shelf Lightning to 30-pin adapter for connection)
Multiple Patients Use	Yes (Allow multiple patients to use the same Smart Cable and Application, but with different user IDs)	Same
Data List	List all reading in "Diary"	Same
Target Levels	High and low blood glucose target levels can be changed: Before Meal, After Meal, Bed Time	High and low blood glucose target levels can be changed: Before Meal, After Meal
Daily Activities Records	Yes	Yes
Transferred Data Time Periods	14, 30, 60, and 90 day time periods for displaying the transfer blood glucose levels cannot be changed	Same
Data Base	Can Set up multiple patient data bases	Same
Average Data Display	Yes	Yes
Invite Others to View Data through Authorization	Yes (through invitation feature)	No
Data Reports and Charts	Data List, statistics, Pie Chart, Line graph by time of the day and by date for the selected time periods (14 days, 30 days, 60 days, 90 days).	Data List, statistics, Pie Chart, Line graph by time of the day and by date for the selected time periods (two weeks, 1 month)
Change Meter Settings	Does not allow change to meter settings	Same

Password	Password protection on the App	Same
Database Providers	Amazon Web Service	Unknown
Associate a Meter to Specific Personal Account	No association	No association

8. Discussion of Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Diabetes Management System, and the GE Diabetes Management System.

Data Transmission Memory Rollover Synchronization Verification
Data transmission accuracy and memory data rollover synchronization were tested at each compatible meter's full data memory capacity to ensure successful upload and storage into software database of the Health2Sync Mobile App Management System. Software test used 2 meters per model, 6 meters in 3 models with fully loaded data; and 15 meters in 3 models with partially loaded data.

Meter	Expected Test Result	Result
OMNIS Health Embrace BGMS Meter	Full set of data (300 records) transferred from meter to Mobile App was accurately downloaded	Pass
	Meter memory data rollover accurately transmitted to Mobile App with additional new data	Pass
OMNIS Health Embrace EVO BGMS Meter	Full set of data (300 records) transferred from meter to Mobile App was accurately downloaded	Pass
	Meter memory data rollover accurately transmitted to Mobile App with additional new data	Pass
Medline EvenCare G2 BGMS meter	Full set of data (300 records) transferred from meter to Mobile App was accurately downloaded	Pass
	Meter memory data rollover accurately transmitted to Mobile App with additional new data	Pass

Discussion of Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence (Cont.):

User Performance Evaluation:

The User (Layperson) Performance Evaluation of Health2Sync Mobile Application and Smart Cable study included 21 participants of varying age, sex, background, education level, and work experience.

The study demonstrates that English-speaking/reading laypersons are able to follow user instructions to successfully download Health2Sync Mobile Application, connect Smart Cable with compatible meter to smartphone and import data to Health2Sync Mobile Application for diabetes management.

Electromagnetic Compatibility (EMC):

To evaluate the compliance of safety requirements for electrical equipment – Smart Cable, the certificate testing and compliance reports were performed by Compliance Certification Services Inc. Taiwan Wugu Laboratory.

The EMC reports confirmed that Smart Cable met performance criteria indicated by the standards.

Readability Assessment:

The Readability Assessment Tests were performed using the Flesch-Kincaid Grade Level Score to evaluate the readability of the Smart Cable Quick Start guide and Mobile App User Manual.

The obtained results demonstrate that Smart Cable Quick Start guide and Mobile App User Manual each received a Flesch-Kincaid Grade Level that indicates each text is expected to be understood by an average student in the eighth grade. The assessments ranged from 7.7 to 7.9 and therefore each text meets the criteria.

9. Conclusion:

Results of performance evaluation of the Health2Sync Mobile App and Smart Cable with compatible blood glucose meters demonstrate that the subject devices are substantially equivalent to the predicate devices.